

Attorney Docket No.: 57458-CIP2-C(46453)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: P. Baraldi

U.S.S.N.: - **GROUP ART UNIT:** 1624 (presumed)

FILED: Herewith **EXAMINER:** T. Truong (presumed)

FOR: ALLOSTERIC ADENOSINE RECEPTOR MODULATORS

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV342612850US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on 9.15.03.

By: /

Donna R. Davis

MAIL STOP PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

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II. COPIES

- a. _____ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. X This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. 09/811,679, filed on March 19, 2001. The following references were submitted to, and/or cited by, the Office in the prior application (s) and, therefore, are not required to be provided in this application.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. X Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. _____ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. _____ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)

(check one box)

- a. X within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1). No fee or certification is required.
- b. _____ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b) (2). No fee or certification is required.

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c. Before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
or
b. See the certification below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

Attorney Docket No.: 57458-CIP2-C

P. Baraldi

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c. _____

Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

_____ Please charge Deposit Account No. 04-1105 in the amount of \$180.00 for the above-indicated fee. A triplicate copy of this paper is attached.

X _____

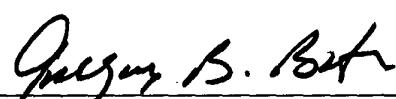
No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. **04-1105**.

Respectfully submitted,

Date: 9/15/03

By:



Gregory B. Butler, Ph.D., Esq.
Reg. No.: 34,558
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FORM PTO-1449			DOCKET NO.:	SERIAL NO.:
			57458-CIP2-C(46453)	-
			APPLICANT(S): P. Baraldi	
			FILING DATE: HEREWITH	GROUP NO.: 1624 (PRESUMED)

UNITED STATES PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
AA		US 6,177,444 B1	01/23/01	Baraldi	514	301	05/07/99

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

CA	Copy of International Search Report dated 06 August 2003, issued in corresponding PCT Appl. No. PCT/US02/08821, filed 3/19/02.
CB	"Kollias-Baker, et al., "Agonist-Independent Effect of an Allosteric Enhancer of the A ₁ Adenosine Receptor in CHO Cells Stably Expressing the Recombinant Human A ₁ Receptor ¹ , Journal of Pharmacology and Experimental Therapeutics, 1997, Vol. 281, No. 2, pp. 761-768.
CC	van der Klein, et al., "Allosteric Modulation of the Adenosine A ₁ Receptor. Synthesis and Biological Evaluation of Novel 2-Amino-3-benzylthiophenes as Allosteric Enhancers of Agonist Binding, Journal Med. Chem., August 19, 1999, Vol. 42, pp. 3629-3635.
CD	Tinney, et al., "Synthesis and Pharmacological Evaluation of 2,3-Dihydro-1H-thieno[2,3-e][1,4]diazepines," Journal of Medicinal Chemistry, 1974, Vol. 17, No. 6, pp. 624-630.
CE	Baba, et al., "Studies on Disease-Modifying Antirheumatic Drugs. IV. Synthesis of Novel Theno[2,3-b: 5,4-c] Dipyridine Derivatives and Their Anti-inflammatory Effect," Chem. Pharm. Bulletin, July 1999, Vol. 47, No. 7. Abstract.

EXAMINER:	DATE:
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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT			DOCKET NO.:		SERIAL NO.:			
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UNITED STATES PATENT DOCUMENTS								
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE	
	AA	US 6,323,214 B1	11/27/01	Baraldi	514	301		
	AB	US 6,194,449 B1	02/27/01	Baraldi	514	447		
	AC	5,939,432	08/17/99	Baraldi	514	301		
	AD	5,585,385	12/17/96	Natsugari, et al.	514	300		
	AE	5,026,698	06/1998	Fujikawa, et al.				
	AF	5,747,486	05/1998	Sohda	514	211		
	AG	5,593,988	01/1997	Tahara	514	219		
	AI	3,558,606	01/1971	Tinney	260	239.3		
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO	
	BA	50,011,397	04/1995	JAPAN				
	BB	3,724,031	01/1998	GERMANY				
	BC	96/14319	05/1996	PCT				
	BD	5,345,785	12/1993	JAPAN				
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	BG	407,955	01/1991	EUROPE				
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	BJ	2,233,457	02/1973	GERMANY				
	BK	8,337,583	12/1996	JAPAN				

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INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) 57458-CIPZ-C(46453)	Application Number
		Applicant(s) BARALDI	
		Filing Date HEREWITH	Group Art Unit 1624 (PRESUMED)
*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
CA	CORRAL, ET AL., "REACCIONES DE BISCHLERY DE FRIEDLANDER CON 2-AMINO-3-AROIL-TIOFENOES," AFINIDAD, MARCH - APRIL (1978).		
CB	CAS FOR ROUTH, ET AL., "TACHYKININ RECEPTORS IN THE SPINAL CORD, PROGRESS IN BRAIN RESEARCH," VOL. 104, PP 93-108.		
CC	CAS FOR CHESSELET, ET AL., "ISCHEMIC DAMAGE IN THE STRIATUM OF ADULT GERBILS: RELATIVE SPARING OF SOMATOSTATINERGIC AND CHOLINERGIC INTERNEURONS CONTRASTS WITH LOSS OF EFFERENT NEURONS," EXPERIMENTAL NEUROLOGY, VOL. 110, NO. 2, PP 209-218.		
CD	CAS FOR CRAGG, ET AL., TACHYKININ ANTAGONISTS IN CARTOID BODY RESPONSES TO HYPOXIA AND SUBSTANCE P IN THE RAT," RESPIRATION PHYSIOLOGY, VOL. 95, NO. 3, PP 295-310.		
CE	CAS FOR BENEDEK, ET AL., "POTENTIATION OF THERMOREGULATORY AND ANALGESIC EFFECTS OF MORPHINE BY CALCIUM ANTAGONISTS," PHARMACOLOGICAL RESEARCH COMMS., VOL. 16, NO. 10, PP 1009-1018.		
CF	CAS FOR GHIO, ET., "CLINICAL EVALUATION OF CALCIUM-ANTAGONIST DRUGS," J OF CARDIOVASCULAR PHARMACOLOGY, VOL. 20, PP S71-74.		
CG	CAS FOR ZHOU, ET AL., "EFFECTS OF CALCIUM BLOCKERS ON THE PERFORMANCE OF LEFT AND RIGHT VENTRICLES DURING ACUTE HYPOXIA," SHENG LI HSEUH PAO, VOL. 44, PP 237-243.		
CH	CAS FOR UENO, ET AL., "SIMULTANEOUS DETERMINATION OF A NEW DIHYDROPYRIDINE CALCIUM BLOCKER AND ITS PYRIDINE METABOLITE IN DOG PLASMA BY COLUMN SWITCHING HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY WITH ELECTROCHEMICAL AND ULTRAVIOLET DETECTION," ANALYTICAL SCIENCE.		
CI	KOLLIAS-BAKER, ET AL., "ALLOSTERIC ENHANCER PD 81,723 ACTS BY NOVEL MECHANISM TO POTENTIATE CARDIAC ACTIONS OF ADENOSINE," CIR. RESEARCH, VOL. 75, NO. 6, PP 961-971 (1994).		
CJ	KOLLIAS-BAKER, ET AL., "THE ALLOSTERIC ENHANCER, PD 81,723, POTENTIATES THE CARDIAC EFFECTS OF ADENOSINE BY ENHANCING THE BINDING OF AGONISTS TO A1 ADENOSINE RECEPTORS," A DISSERTATION PRESENTED TO THE GRADUATE SCHOOL OF THE UNIVERSITY OF FLORIDA (1994).		
CK	LEUNG, ET AL., "ENHANCEMENT OF ADENOSINE A1 RECEPTOR FUNCTIONS BY BENZOYLTHIOPHENES IN GUINEA PIG TISSUES IN VITRO," ARCHIVES OF PHARMACOLOGY, VOL. 352, NO. 2, PP 206-212.		
CL	MIZUMURA, ET AL., "PD 81,723 AN ALLOSTERIC ENHANCER OF THE A1 ADENOSINE RECEPTOR, LOWERS THE THRESHOLD FOR ISCHEMIC PRECONDITIONING IN DOGS," CIR. RESEARCH, VOL. 79, NO. 3, PP 415-423 (SEPTEMBER 1996).		
EXAMINER		DATE CONSIDERED	
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance or not considered. Include copy of this form with next communication to applicant.</p>			

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CM	MUDUMBI, ET AL., "CARDIA FUNCTIONAL RESPONSES TO ADENOSINE BY PD 81,723, AN ALLOSTERIC ENHANCER OF THE ADENOSINE A1 RECEPTOR," AMERICAN JOURNAL OF PHYSIOLOGY, VOL. 264, PP H1017-H1022.		
CN	NAKANISHI, ET AL., "STUDIES ON PCYCHOTROPIC DRUGS. 18.1 SYNTHESIS AND STRUCTURE-ACTIVITY RELATIONSHIPS OF 5-PHENYL-1,3-DIHYDRO-2H-THIENO[2,3-E][1,4]DIAZEPIN-2-ONES," JOURNAL OF MEDICINAL CHEMISTRY, VOL. 16, NO. 3, PP 214-219, 1973.		
CO	ROBBA, ET AL., "NO. 144-THIENOPYRIMIDINES. IX - ETUDE DE LA THIENO[2,3-D]PYRIMIDINES ET DE SES DERIVES," BULETINE DE LA SOCIETE CHIMIQUE DE FRANCE, PP 761-764 (1976).		
CP	AMOAH-APRAKU, ET AL., "SELECTIVE POTENTIATION BY AN A1 ADENOSINE RECEPTOR ENHANCER OF THE NEGATIVE DROMOTROPIC ACTION OF ADENOSINE IN THE GUINEA PIG HEART," THE JOURNAL OF PHARM. AND EXPERIMENTAL THERAPEUTICS, VOL. 266, NO. 2, PP 611-617 (1993).		
CQ	BHATTACHARYA, ET AL., "EFFECTS OF LONG-TERM TREATMENT WITH THE ALLOSTERIC ENHANCER, PD 81,723, IN CHINESE HAMSTER OVARY CELLS EXPRESSING RECOMBINANT HUMAN A1 ADENOSINE RECEPTORS," MOLECULAR PHARM., VOL. 50, PP 104-111 (1996).		
CR	BHATTACHARYA, ET AL., "THE ALLOSTERIC ENHANCER, PD 81,723, STABILIZES HUMAN A1 ADENOSINE RECEPTOR COUPLING TO G PROTEINS," BIOCHIMICA ET BIOPHYSICS ACTA, 1265: PP 15-21, 1995.		
CS	BRUNS, ET AL., "ALLOSTERIC ENHANCEMENT OF ADENOSINE A1 RECEPTOR BINDING AND FUNCTION BY 2-AMINO-3-BENZOYLTHIOPHENES," MOLECULAR PHARM., VOL 38, NO. 6, PP 939-949 (1990).		
CT	BRUNS, ET AL., "STRUCTURE-ACTIVITY RELATIONSHIPS FOR ENHANCEMENT OF ADENOSINE A1 RECEPTOR BINDING BY 2-AMINO-3-BENZOYLTHIOPHENES," MOLECULAR PHARM., VOL 38, PP 950-958 (1990).		
CU	CAO, ET AL., "ADENOSINE A1 RECEPTOR ENHANCER, "PD 81,723 AND CEREBRAL ISCHEMIA/REPERFUSION INJURY IN THE GERBIL," GENERAL PHARMACOLOGY, VOL. 26, NO. 7, PP 1545-1548 (1995).		
CV	DENNIS, ET AL., "MODULATION OF ATRIOVENTRICULAR NODAL FUNCTION BY METABOLIC AND ALLOSTERIC REGULATORS ENDOGENOUS ADENOSINE IN GUINEA PIG HEART," CIRCULATION, VOL. 94, NO. 10, PP 2551-2559 (1996).		
CW	FORTEA, "THIENO[2,3-D]PYRIMIDINE3-OXIDES. SYNTHESIS AND N-OXIDE REACTIONS OF 4-PHENYL-AND-4-AMINO-THIENO[2,3-D]PYRIMIDINE3-OXIDES," JOURNAL FUR PRAKTISCHE CHEMIE, BAND 317, HEFT 5, PP 705-711 (1975).		
CX	HROMATKA, ET AL., UBER DIE NITRIERUNG VON 7-CHLOR-5-PHENYL-1H-THIENO[2,3-E]1,4-DIAZEPIN-2(3H)-ON, "MONATSHEFT FUR CHEMIE, VOL. 104, PP 709-714 (1973).		
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CY	<p>"JANUSZ, ET AL., "FUNCTIONAL ACTIVITY OF THE ADENOSINE BINDING ENHANCER, PD 81,723, IN THE IN VITRO HIPPOCAMPAL SLICE," BRAIN RESEARCH, VOL. 567, PP 181-187, (1991).</p>		
CZ	<p>KOLLIAS-BAKER, ET AL., "NOVEL APPROACH FOR ENHANCING ATRIOVENTRICULAR NODAL CONDUCTION DELAY MEDIATED BY ENDOGENOUS ADENOSINE," CIR. RESEARCH, VOL. 75, NO. 6, PP 972-980 (1994).</p>		
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